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Docket No. JJM-381

#15/Brief

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Paul W. Watt et al.  
Serial No. : 09/164,793 Art Unit: 3731  
Filed : October 1, 1998 Examiner: G. Jackson  
For : BIOPOLYMER SPONGE TUBES, SURGICAL STAPLERS AND  
METHODS OF USE THEREOF

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May 22, 2001

(Date)

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Name of applicant, assignee, or Registered Representative

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(Signature)

May 22, 2001

(Date of Signature)

Assistant Commissioner for Patents  
Washington, D.C. 20231

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

**APPELLANT'S BRIEF (37 C.F.R. 1.192)**

This is an appeal from the final rejection mailed November 29, 2000, a Notice of Appeal  
having been submitted to the USPTO February 22, 2001. Appellant's Brief is being submitted on

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May 22, 2001. A one-month extension of time is concurrently submitted with Appellant's Brief to extend the time for response from April 22, 2001 to May 22, 2001.

The fees required under Section 1.17(f), and any required petition for extension of time for filing this brief and fees therefor, are addressed with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate. (37 CFR 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. REAL PARTY INTEREST

The real party in interest of the subject patent application is Ethicon, Inc., having a principal place of business at U.S. Route 22, Somerville, NJ 08876.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

3. STATUS OF CLAIMS

3.1. Claims 1-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 5,843,096 (Igaski) in view of US 3,157,524 (Artandi) and US 5,660,857 (Haynes).

4. STATUS OF AMENDMENTS

An amendment after Final Rejection had been filed concurrently with the filing of the Notice of Appeal on February 22, 2001. The claims involved in the appeal reflect these amendments although Appellant has not received confirmation that these amendments have been entered either by Advisory Action or returned phone call from the Examiner of record to the undersigned Attorney .

5. SUMMARY OF INVENTION

The present invention provides a biopolymer sponge tube closed at one end and which is of uniform composition and construction (claim 1 and specification page 3, lines 23-24).

The present invention also provides for a surgical stapler comprising a staple cartridge and an anvil, and having a biopolymer sponge tube (which need not be closed at one end) fitted over the staple cartridge and/or over the anvil. Preferably, biopolymer sponge tubes are fitted over each of the staple cartridge and the anvil. Preferably, the biopolymer sponge tube or tubes are closed at one end. (Specification, page 3, line 30 to page 4, line 5)

The present invention further provides a method of the use of a biopolymer sponge tube for the preparation of a surgical stapler as above for use in surgery. (Specification, page 4, lines 7-9).

6. STATEMENT OF ISSUES

6.1 Whether claims 1-25 are unpatentable under 35 U.S.C. 103(a) over US 5,843,096 (Igaski) in view of US 3,157,524 (Artandi) and US 5,660,857 (Haynes).

7. GROUPING OF CLAIMS

For the purposes of the appeal, the following groups of claims do not stand or fall together.

7.1 Group I, includes claims 1-10 directed toward biopolymer sponge tubes which are closed at one end.

7.2 Group II, includes claims 11-17 directed toward a surgical stapler having a biopolymer sponge tube fitted over the staple cartridge and/or over the anvil.

7.3 Group III, includes claims 18-25 directed toward a method of stapling mammalian tissue.

Groups I, II, and III, are separately patentable. Group II is separately patentable over Group I as Group II is not directed only to closed-end sponge tubes as Group I is and Group II includes sponge tubes without any closed ends. Therefore Group I and II are separately patentable.

Group III is separately patentable from Groups I and II as Group III is directed to a method of stapling mammalian tissue. The closed-end sponge tubes of Group I is not restricted to any particular use and the stapler of Group II is not restricted for use with stapling of mammalian tissue. Therefore, the claims of Group III are separately patentable over the claims of Groups I and II.

Therefore, based on the foregoing, the claims of Groups I, II and III are separately patentable from among themselves.

8. ARGUMENTS

8.1 Claims 1-25 are not obvious under 35 U.S.C. 103(a) over US 5,843,096 (Igaki) in view of US 3,157,524 (Artandi) and US 5,660,857 (Haynes).

The Appellant submits the Examiner's §103(a) rejection of claims 1-25 is improper for the following reasons.

Igaki discloses a suturing material "formed by sewing a sheet shape suturing material into a bag shape having a closed leading end by using a suturing thread" (col. 2, lines 6-8). However, clearly the disclosed "sutured bag" of Igaki is not a "sponge tube" as claimed by Appellant.

Artandi relates to collagen sponges and the preparation thereof. However, there appears to be no disclosure relating to forming sponge tubes as claimed by Appellant.

Haynes relates to biopolymer composites, but again, there appears to be no disclosure relating to forming sponge tubes as claimed by Appellant.

The Examiner originally cited Igaki for disclosing "a tube having one end closed formed of chitin. However, a sponge texture is not clearly disclosed." The Examiner cited Artandi and Haynes for disclosing formation of "collagen material with sponge-like texture for the medical purposes." The Examiner then concludes obviousness based on the foregoing disclosures.

In the final Rejection, the Examiner maintains that the:

Igaki et al. device is clearly tubular shaped and read on that aspect of the claim. In this instance, the examiner sees the tubular shape of the applicant's device and the bag shape of Igaki et al as one and the same. Igaki et al recognize and solve the same problem identified by the applicants except that different material is used on the stapler. The patent of Artandi clearly suggests collagen sponge tubes because of outstanding characteristics for absorption and strength.

The Examiner believes that it would have been obvious to one having ordinary skill in the art to form Igaki's device of collagen foam as taught by Artandi et al.

For, these reasons this action is made final ..

Appellant respectfully submits as noted above, that Igaki does not disclose a "tube" but only a "suturing material formed by sewing a sheet shape suturing material into a bag shape having a closed leading end by using a suturing thread." Further Igaki contains no suggestion to use or form a "sponge tube". The Examiner's reading of Igaki's "sutured bag" to disclose a tube is not seen. According to The American College dictionary, Third Edition, a tube is defined as "a hollow cylinder, esp. one that conveys a fluid or functions as a passage".

Appellant further contends that nowhere in the prior art is there suggestion to form a "closed-end" sponge tube as claimed. The claimed closed-end sponge tube is of uniform composition and construction (not requiring sutures as in the "bag" of Igaki). Once the tube is removed from the mold and is dried, no further steps are required to form the closed end. The collagen tubes disclosed in Artandi would still require closure as Artandi only discloses porous collagen tubes that are opened at both ends (see EXAMPLE XI, where the tube is formed from a glass rod/rubber tube combination; once the collagen tube is formed over the glass rod/rubber tube assembly, "the rubber tube with the collagen tube is carefully slid off the glass rod and the rubber

tube is removed from the interior of the collagen tube by pulling both ends of the rubber tube, thereby stretching the rubber tube and reducing its diameter", therefore, the collagen tubes of Artandi must be opened at both ends).

Clearly, neither Igaki nor its combination with Artandi and Haynes renders Appellant's invention obvious. Therefore, this rejection is respectfully requested to be reversed.

#### 8.6 CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to claims 1-25 are respectfully requested.



9. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

Respectfully submitted,



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**APPENDIX OF CLAIMS INVOLVED IN THE APPEAL**

1. A biopolymer sponge tube which is closed at one end and which is of uniform composition and construction.
2. A biopolymer sponge tube according to claim 1 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.
3. A biopolymer sponge tube according to claim 2, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.
4. A biopolymer sponge tube according to claim 3, wherein the biopolymer consists essentially of collagen.
5. A biopolymer sponge tube according to claim 1 and further comprising a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.
6. A biopolymer sponge tube according to claim 1 which is fully bioabsorbable in a mammalian body.
7. A biopolymer sponge tube according claim 1 having an average internal diameter of from 3mm to 30mm.

8. A biopolymer sponge tube according claim 7 having a substantially uniform uncompressed wall thickness of from 1 to 4mm.

9. A biopolymer sponge tube according to claim 1, wherein the ratio of length to average external diameter is in the range of 2:1 to 10:1.

10. A biopolymer sponge tube according to claim 1, wherein the biopolymer comprises collagen having droplets of lipids dispersed therein.

11. A surgical stapler comprising a staple cartridge and an anvil, and having a biopolymer sponge tube fitted over the staple cartridge and/or over the anvil.

12. A surgical stapler according to claim 11 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.

13. A surgical stapler according to claim 12, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.

14. A surgical stapler according to claim 13, wherein the biopolymer consists essentially of collagen.

15. A surgical stapler according to claim 11 wherein the biopolymer sponge tube further comprises a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.

16. A surgical stapler according to claim 11 wherein the biopolymer sponge tube is fully bioabsorbable in a mammalian body.

17. A surgical stapler according to claim 11, wherein the biopolymer comprises collagen having droplets of lipids dispersed therein.

18. A method for stapling mammalian tissue comprising the steps of:  
placing the tissue between a staple cartridge and an anvil in a surgical stapler;  
fitting a (closed-end) biopolymer sponge tube of (uniform composition and construction) over the staple cartridge and/or over the anvil; and

firing at least one staple from the staple cartridge through the biopolymer sponge tube and through the tissue to thereby attach the biopolymer sponge tube to the tissue.

19. A method according to claim 18 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.

20. A method according to claim 19, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.

21. A method according to claim 20, wherein the biopolymer consists essentially of collagen.

22. A method according to claim 18 wherein the biopolymer sponge tube further comprises a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.
23. A method according to claim 18 wherein the biopolymer sponge tube is fully bioabsorbable in a mammalian body.
24. A method according to claim 18 wherein the tissue is lung tissue being joined in a lung resection.
25. A method according to claim 18 wherein the biopolymer sponge tube comprises collagen containing a lipid material dispersed therein.